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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAKH, YELENA G	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/827,045	Applicant(s) DEVLIN ET AL.	
	Examiner Yelena G. Gakh, Ph.D.	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondenc address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☒ Claim(s) *1,2 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 May 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-29 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-29 of prior U.S. Patent No. 09/725,621. This is a double patenting rejection.

Specification and Drawings

3. The specification and/or Figure 1 are objected to since there is a discrepancy between the description of Figure 1 in the specification and the drawing itself. The specification discloses that Figure 1 shows the elements of conventional automatic chemical analyzer 10, which according to the drawing includes element 50. The specification further discloses element 50 as inventive. Either the specification should be corrected by withdrawing the term "conventional" from describing automatic analyzer 10, or the drawing should be changed so that number 10 points exclusively to the parts of the conventional analyzer, excluding part 50.

Claim Objections

4. Claims 1-2 and 30 are objected to as not reciting active method steps according to the US patent practice, i.e. after the preamble of the claim and the word "comprising", which makes the language of the claims unclear.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-12, 15-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method comprising an analyzing step, does not reasonably provide enablement for the method the only step of which is retaining the sample in the analyzer (or storage). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims recite the method for additional testing, however no testing is recited in the method steps, which makes additional analysis of the specimen impossible.

Claims 26 and 27 recite the protective film having adhesive on one surface. The specification does not describe, what is the function of the adhesive, and which side of the film is adhesive – the one that is closer to the specimen? If the adhesive is in a contact with the specimen, it can easily contaminate the latter. The specification does not adequately disclose neither the function of the adhesive film, nor how it covers the specimen and how it may protect the specimen when it may itself contaminate the specimen if is in a direct contact with the latter.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, because it does not recite any method steps.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-12, 15-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 do not recite active method steps after the word "comprising", which makes it unclear, what should be considered a preamble of the claims, and what is their body, in other words, what are the real method steps.

Claims 1-12, 15-29 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: testing the patient specimen in the analyzer, which is the essence of the method.

Claim 2 is completely unclear. It is not apparent, which method steps are comprised in the method claimed, at which point the additional test is taken and for which sample, since two different aliquots are recited in the claim.

A storage compartment of claims 3-12 can be interpreted as a sample tube (cuvette, well, etc.), since the claims recite that the liquid patient's specimen is retained within a storage compartment, without reciting any other specimen holders. Such claim language renders them unclear, and therefore the correction of the claim language is required.

In claims 8-11 it is not clear, how the liquid patient's specimen can be "marked to determine if an aliquot is retained in storage". Does it mean that additional reagents are added to the specimen? How do they determine if the aliquot is retained in the storage?

In claim 21 it is not clear, how a plurality of aliquots can be retained in one aliquot storage vessel? The expression "an open aliquot storage vessel" recited in the claim brings again the question on what is meant by the term "storage" in preceding claims.

Claims 22-29 are not clear as what is meant my covering the specimen with a protective film. According to the language of claim 1, the patient's specimen is a liquid (an aliquot of the specimen is taken for the analysis). Therefore, it is not clear, how the specimen itself, rather than its holder, can be covered with the protective film. The language of the claims renders them unclear and indefinite.

Claim 30 does not recite any method steps and therefore it is not clear, what the method comprises.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by Mazza et al. (US 5,350,564).

Mazza discloses, "the present invention relates to an adaptive, versatile conveyor system for feeding individual sample tubes, cells, cuvettes, and the like (hereinafter collectively referred to as "sample tubes") each held in an individual prismatic sample tube carrier, either from associated groups or batches which are taken in regular order, or from a stat sample area taken with priority; identifying the individual sample tubes; conveying and/or temporarily storing the individual sample tubes as required; transferring the individual sample tubes to and from one or more associated analysis modules of the apparatus as appropriate; *retaining the individual sample tubes in temporary storage while test results are obtained, and returning the individual sample tubes to associated groups in response to an indication that analysis of a particular sample is complete and verified as reliable*. The present invention has particular utility for use in automated chemical analyzers and related equipment for analysis and testing of blood, physiological fluids, and other biological samples" (col. 1, lines 18-38); "the carriers are individually fed to a rotator assembly which provides both for the *reading of a bar code tag on the sample tube* in the carrier, and the rotational orientation of the carrier in a particular presentation" (col. 5, lines 20-24). Sample carriers returned from an analyzer to the loop conveyor are retained thereon, along with incoming samples en route to an analyzer, and priority stat samples which will be received by an analyzer prior to the rank and file samples, until the results of the tests on the sample are confirmed. Thus, the loop conveyor provides a dwell capacity in association with the analyzer. This dwell capacity also allows rank and file samples to be held in abeyance on the loop conveyor while stat samples traverse the conveyor immediately en route to the analyzer. *In the event the test results are not confirmed, the*

particular sample may be fed from the loop conveyor back to the analyzer for a second or subsequent testing" (col. 5, lines 33-43).

"The entire operation of the conveyor is under the control of a dynamic controller so that each discreet action with respect to a sample carrier from the time its sample is identified until the sample test results are verified and the carrier is off loaded is tracked. Thus, test results are easily correlated with a particular sample and patient. Also, the location of each sample on the loop conveyor, and of vacant receptacles, which are available for receipt of a stat or of a rank and file sample, is always recorded. *This feature of the conveyor along with its storage and dwell time feature makes possible the recall to an analyzer module of any particular sample in the event the results of a test are not verified as reliable*. This latter feature is of high importance with stat samples. If the test results for any stat sample are not reliable, the sample will be recalled to the analyzer and retested. Only when the test results of each sample are verified will the sample be delivered to the off-loading area" (col. 5, lines 56-68, col. 6, lines 1-6).

11. **Claims 2, 4, 6, 8, 10, 12, 14, 16, 18 and 20** are rejected under 35 U.S.C. 102(b) as being anticipated by Chae et al. (US 4,274,744).

Chae teaches a method of additional testing of the patient's specimen aliquots in open cuvettes in the analyzer after predetermined time, e.g. in case of prothrombin tests, when the specimen is kept in the environmentally controlled storage and the aliquots are additionally tested according to the pre-programmed schedule after being retained in the controlled storage compartment for a predetermined time (Abstract, Figure 1, col. 2, lines 15-22).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. **Claims 3, 5, 7, 9, 11, 13, 15, 17, 19 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza in view of Chae.

Mazza does not specifically disclose retaining the specimen, which will be additionally analyzed, in the environmentally controlled storage compartment.

Chae discloses such storage compartment in his analyzer.

It would have been obvious for anyone of ordinary skill in the art to slightly modify Mazza's method by replacing his temporary storage loop conveyer with Chae's storage compartment, because additional or repeated tests may be performed in a longer period of time then suggested by Mazza, which requires controlled conditions for storing valuable biological samples, as disclosed by Chae.

16. **Claims 22, 24, 26 and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza in view of well known prior art, e.g. Boosalis et al. (US 4,362,698).

Although Mazza does not specifically indicate using a protective film (layer, lid, foil, etc.), which can be easily removed or pierced, their use for covering the samples to be analyzed are well known in the art, as disclosed by e.g. Boosalis.

While Boosalis discloses a more complex cover for fluid sample cups, which serves many purposes and contains several layers, including film, adhesive tape, etc., it would have been obvious for anyone of ordinary skill in the art to use any simple cover for sample in Mazza's method, including film, foil, plastic, etc., which is just one layer of Boosalis' cover and which may serve exclusively for protection of the samples and, on the other hand, be easily removed or pierced, because it is a conventional way of protecting samples of biological analytes from contamination during analysis.

17. **Claims 1-29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Windisch et al. (US 5,110,743) in view of Mazza.

Windisch discloses a method and apparatus for storing and mixing blood samples, which "renders possible a wide flexibility or variation in the operation of the storage and mixing apparatus 180 in such a manner that there can be effectively satisfied practically all external requirements as concerns organization of the delivery of the blood samples (routine or standard blood sample analysis or special blood sample analysis as in the case of an emergency situation or condition), the operating or working sequence of the blood sample analysis and as far as the equipment structure is concerned, the course or pattern of operation of the storage and mixing apparatus 180 which processes the blood samples to be analyzed. The proposed storage and mixing apparatus 180 and possible modifications thereof thus fulfill all of the requirements which are placed upon an interface between computable or predictable high automation requirements and a non-computable or non-predictable environment or surroundings" (col. 13, lines 53-68 and col. 14, lines 1-7). He further indicates, "after expiration of the contemplated blood sample mixing or moving time, then the blood sample, such as the blood samples 140, can be selectively rotated about the lengthwise axis of the associated stoppered test-tube like container of such blood sample 140 so that there can be read the blood identification data or marking. In so doing, there can be decided whether the identified blood sample should be evaluated or simply eliminated. By means of the blood sample removal or extraction device 7 there is removed a part of the blood from the stoppered test-tube like container housing the blood sample 140. For that purpose, the mixing disc or disc means 17 is brought to standstill. This blood sample removal or extraction operation is accomplished through the stoppered container or vessel in that the hollow needle or needle member 114 pierces the flexible stopper or rubber cap

141 (see FIG. 10)" (col. 14, lines 29-46). "Moreover, in accordance with a further exemplary embodiment of the inventive apparatus the stored data of a blood sample identification can be used for the entire control operation" (col. 14, lines 65-68). Although Windisch does not particularly teach controlled conditions of the storage compartment, he recognizes that the blood samples cannot stay for a long period of time, since the blood may stratify (col. 1, lines 18-20); therefore it would have been obvious for anyone of ordinary skill in the art to make the storage housing of Windisch environmentally controlled, because this allows holding routine samples for longer periods of time e.g. in case of many emergency samples.

Windisch does not specifically teach a method for additional testing the same patient's specimen.

Mazza teaches an additional testing of the patient's specimen especially if it does not show reliable results.

It would have been obvious for anyone of ordinary skill in the art to apply Windisch's method for the case disclosed by Mazza for additional testing the same patient's specimen or another aliquot of the patient's specimen, because Windisch's method covers such planned delivery of the patient's samples from the storage housing, or returning them to the storage housing in the case of emergency samples or in the case of unreliable data, as indicated by Mazza. It would have been obvious for anyone of ordinary skill in the art to keep the test tubes with the specimen covered with various type of protective film, which can be easily removed or pierced, because this is a conventional way of protecting biological samples from contamination.

18. **Claims 30-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorne et al. (US 4,678,752).

Thorne discloses an automatic random access analyzer comprising an environmentally controlled (col. 10, lines 60-67) incubation storage area 18 within the analyzer for storing a plurality of reagent packages comprising reagent solutions, with the packages having barcode labels 46 with the information on expiration date (col. 5, lines 60-68). The reagents are automatically extracted for further use in automated analyzer.

Although Thorne does not specifically disclose that such extraction occurs before the expiration date, it would have been obvious for anyone of ordinary skill in the art to use (i.e. extract) reagents before the expiration date, which is read by the scanner. It would have been

obvious to apply the method of extraction taught by Thorne to formulations, because they are biologically active reagents which may be applied in assays the same way Thorne discloses for his analyzer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (703) 306-5906. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Yelena G. Gakh
9/30/03